

510(k) Summary

JUL 26 2011

1. Submitter's Name and Address

Advancis Medical
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Nottinghamshire. NG17 7JZ

Contact Person: Toni Miller PhD
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Date Prepared 8 November 2010

2. Device Name

Trade Name: **Activon Tube™ Sterile 100% Manuka Honey**
Common: Dressing, Wound
Classification Name: Dressing, Wound
Regulatory Class: Unclassified
Product Code: FRO

3. Predicate Devices

Activon Tube™ Sterile 100% Manuka Honey is substantially equivalent to the following Manuka Honey wound dressings:

- OTC Elasto-Gel Manuka Honey Wound Dressing K102478
- Manukapli Wound Dressing K092689
- Elasto-Gel Manuka Honey Wound Dressing K083334
- Derma Sciences OTC Medihoney Dressings With Active Manuka Honey K081584
- Medihoney Active Manuka (*Leptospermum*) 100% Honey dispensed from a tube K080315

4. Device Description

Activon Tube™ Sterile 100% Manuka Honey is a wound care dressing for use in moist wound management. The **Activon Tube™ Sterile 100% Manuka Honey** is offered as a 0.99 oz (2.8 g) twist off cap squeeze tube for one-time use.

5. Statement of Intended Use

Activon Tube™ Sterile 100% Manuka Honey for Over-the-Counter is intended for the management of normal skin and minor wounds, minor ulcerations, minor burns, minor abraded skin, and minor irritated areas. Under the supervision of a health care professional, **Activon Tube™ Sterile 100% Manuka Honey** may be used for the management of diabetic foot and leg ulcers, leg ulcers (venous stasis ulcers, arterial ulcers and leg ulcers of mixed etiology), pressure ulcers/sores (partial and full thickness), 1st and 2nd degree partial thickness burns, grafted and donor sites, and traumatic and surgical wounds.

Activon Tube™ Sterile 100% Manuka Honey may be applied directly to the wound to fill the wound cavities or to a primary dressing.

6. Technological Characteristics and Substantial Equivalence

Activon Tube™ Sterile 100% Manuka Honey is essentially and substantially identical to the predicate devices in their use of Manuka Honey for moist wound management. Medihoney Active Manuka (*Leptospermum*)100% Honey (K080315) is sterilized by gamma radiation and dispenses Manuka honey from a tube, essentially identically in technology and indications to **Activon Tube™ Sterile 100% Manuka Honey**. The additional predicate devices (K102478, K092689, K083334, K081584) are substantially identical to **Activon Tube™ Sterile 100% Manuka Honey** in their use of active **Manuka Honey** for wound management, but the honey is either presented in a hydrocolloid/gel sheet or part of an absorbent wound dressing.

7. Assessment of Performance Data and Safety

Biocompatibility testing (cytotoxicity, sensitization and irritation) performed with **Activon Tube™ Sterile 100% Manuka Honey** demonstrates that the dressing is safe for its intended use. The performed testing was conducted according to ISO guidelines.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Advancis Medical
% LEC Associates, LLC
Toni Miller, PhD
26 Chestnut Ridge Road, #12
Montvale, New Jersey 07645

Re: K101114
Trade/Device Name: Activon Tube®
Regulatory Class: Unclassified
Product Code: FRO
Dated: July 11, 2011
Received: July 31, 2011

JUL 26 2011

Dear Dr. Miller:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

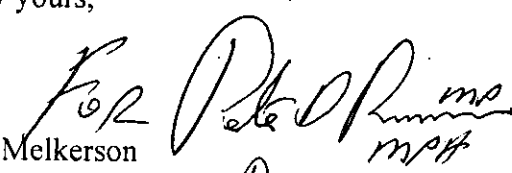
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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K101114

Indications for Use Statement

Device Name: Activon Tube®

Indications for use:

OTC: For minor wounds, minor ulcerations, minor burns, minor abraded skin, and minor irritated areas.

Professional: Intended in the management of:

- diabetic foot ulcers;
- leg ulcers (venous stasis ulcers, arterial ulcers and leg ulcers of mixed etiology);
- pressure ulcers/sores (partial and full thickness);
- 1st and 2nd degree partial thickness burns;
- grafted and donor sites and traumatic and surgical wounds.

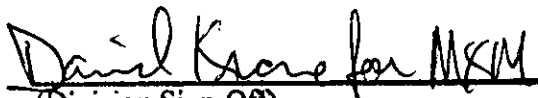
Prescription Use X
(Part 21 CFR 801 Subpart D)

And/Or

Over-The-Counter Use X
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

(Division Sign-Off)
Division of General, Restorative, and
Neurological Devices

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